

### Claims

1. A polypeptide having the antibody binding specificity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least a portion of one of the light chains of clotting factors V and VIII.

2. The polypeptide of claim 1 being the about 46 kDalton HMFG differentiation antigen or an antibody binding functional fragment thereof.

3. The polypeptide of claim 1 having the biological activity of the about 46 kDalton HMFG antigen and/or homology to at least a portion of one of the light chains of clotting factors V and VIII.

4. The polypeptide of claim 1, having the amino acid sequence shown in Table 2 or an antibody binding functional fragment thereof of about 5 to 50 amino acids.

5. A pharmaceutical composition, comprising an antibody binding effective amount of the polypeptide of claim 1; and a pharmaceutically acceptable carrier.

6. A fusion protein, comprising the polypeptide of claim 1; and a second antigenic polypeptide or an antibody binding functional fragment thereof bound thereto.

7. The fusion protein of claim 6, wherein the second antigenic polypeptide has the antibody binding activity of  $\beta$ -galactosidase or a functional fragment thereof.

8. An antibody having specificity for the polypeptide of claim 1 or a functional fragment thereof.

9. The antibody of claim 8, being a monoclonal antibody.

10. The antibody of claim 8, comprising a single chain thereof.

11. The antibody of claim 8 comprising the Fab fragment thereof or a single chain thereof.

12. A pharmaceutical composition, comprising a polypeptide binding effective amount of the antibody of claim 8; and a pharmaceutically acceptable carrier.

13. A method of detecting the presence in a biological sample of a polypeptide having the antibody binding specificity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least one of the light chains of clotting factors V and VIII or a functional fragment thereof, comprising providing a biological sample suspected of comprising the polypeptide;

adding thereto a polypeptide binding effective amount of the antibody of claim 8 under conditions effective to form an antibody-polypeptide complex; and

determining the presence of any complex formed therebetween.

14. The method of claim 13, wherein the sample comprises animal cells, cell extracts or body fluids.

15. A method of determining the presence in a biological sample of epithelial cells, comprising

providing a biological sample suspected of comprising cells of epithelial origin carrying a polypeptide having the antibody binding activity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least one of the light chains of clotting factors V and VIII or a functional fragment thereof;

adding thereto a polypeptide binding effective amount of the antibody of claim 8 under conditions effective to form an antibody-cell polypeptide complex; and

determining the presence of any complex formed therebetween.

16. The method of claim 14, wherein the biological sample comprises a bone marrow sample.

17. A method of determining the presence in a biological sample of epithelial cells, comprising

providing a biological sample suspected of comprising cells of epithelial origin carrying a polypeptide having the antibody binding activity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least one of the light chains of clotting factors V and VIII or a functional fragment thereof;

lysing any cells comprised in the sample to expose the RNA therefrom;

adding thereto a hybridization effective amount of the coding strand of the polynucleotide sequence of claim 28 in single stranded form under conditions effective to hybridize any RNA having a complementary sequence of about at least 15 bases thereto; and

detecting the presence of the polynucleotide-RNA hybrid.

18. A method of determining the presence in a biological sample of epithelial cells, comprising providing a biological sample suspected of comprising cells of epithelial origin carrying a polypeptide having the antibody binding activity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least one of the light chains of clotting factors V and VIII or a functional fragment thereof;

lysing any cells comprised in the sample to expose the RNA therefrom;

adding thereto a hybridization effective amount of an oligoribonucleotide complementary to at least a portion of the polyribonucleotide sequence of claim 31 under conditions effective to hybridize thereto RNA having a complementary sequence of at least about 15 bases; and

detecting the presence of the polyribonucleotide-RNA hybrid.

19. An in vivo method of imaging cells expressing a polypeptide having the antibody binding specificity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least one of the light chains of clotting factors V and VIII in a subject, the method comprising

administering to a subject a polypeptide binding effective amount of the antibody of claim 8 under conditions effective to deliver it to an area of the subject's body suspected of having cells expressing a polypeptide having the binding specificity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least one of the light chains of clotting factors V and VIII to form an antibody-cell polypeptide complex;

administering to the subject a detectable label capable of binding to the antibody at a site other than the binding site for the polypeptide; and

detecting the presence of the label associated with any complex formed in the subject's body.

20. An in vivo method of vaccinating a subject against a polypeptide having the antibody binding specificity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least one of the light chains of clotting factors V and VIII or cells carrying the polypeptide comprising administering to a subject the polypeptide of claim 4 in an amount and under conditions effective to vaccinate the subject against the polypeptide, binding functional fragments thereof,

or cells carrying the polypeptide or fractional fragments thereof.

21. A method of detecting the presence in a biological sample of an antibody having affinity for the about 46 kDalton HMFG differentiation antigen, comprising

providing a sample suspected of comprising the antibody;

adding thereto an antibody binding effective amount of the polypeptide of claim 1 under conditions effective to form an antibody-polypeptide complex; and

determining the presence of any complex formed therebetween.

22. A method of detecting the presence of an antibody having affinity for the about 46 kDalton HMFG differentiation antigen in a sample, comprising

providing a sample suspected of comprising the antibody;

adding thereto an antibody binding effective amount of the fusion protein of claim 6 under conditions effective to form an antibody-fusion protein complex;

adding thereto a second polypeptide binding effective amount of an anti-second polypeptide antibody under conditions effective to form an antibody-fusion protein-antibody complex; and

determining the presence of any antibody-fusion protein-antibody complex formed.

23. An in vivo method of delivering a therapeutic agent to target cells expressing a polypeptide having

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the antibody binding activity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least one of the light chains of clotting factors V and VIII in a patient, comprising

binding to the antibody of claim 8 a therapeutic agent at a site other than the polypeptide binding site;

administering to a subject suspected of carrying the target cells a therapeutically effective amount of the antibody-bound therapeutic agent under conditions effective to deliver the agent to the cells' environment; and

allowing for the antibody carrying the therapeutic agent to bind to the cells' polypeptide to permit the therapeutic agent to exert its effect on the cells.

24. An ex vivo method of delivering a therapeutic agent to target cells expressing a polypeptide having the antibody binding activity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least one of the light chains of clotting factors V and VIII, comprising

obtaining from a subject a biological sample suspected of comprising target cells;

binding a therapeutic agent to the antibody of claim 8 at a site other than the polypeptide binding site;

adding the antibody-bound therapeutic agent to the sample under conditions effective to promote the formation of an antibody-cell polypeptide complex;

allowing the agent to exert its effect on the cells; and

returning the sample to the subject.

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25. A polynucleotide encoding the polypeptide of claim 1 or fragments thereof.

26. A DNA sequence which is complementary to the coding strand of the polynucleotide of claim 25.

27. The polynucleotide of claim 25 having the DNA sequence shown in Table 2 or fragments thereof.

28. The polynucleotide of claim 25 in labeled form.

29. The DNA sequence of claim 26 in labeled form.

30. A polyribonucleotide encoding the polypeptide of claim 1 or fragments thereof.

31. The polyribonucleotide of claim 30 in labeled form.

32. A polyribonucleotide having a sequence complementary to that of the polyribonucleotide of claim 30.

33. The polyribonucleotide of claim 32 in labeled form.

34. A polydeoxyribonucleotide encoding the fusion protein of claim 6.



35. A polyribonucleotide encoding the fusion protein of claim 6.

36. A method of detecting the presence in a sample of a polynucleotide sequence encoding a polypeptide having the antibody binding activity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least one of the light chains of clotting factors V and VIII, comprising

providing a sample suspected of comprising the polynucleotide;

melting double stranded polynucleotide present in the sample;

adding thereto a hybridization effective amount of the DNA sequence of claim 29 under conditions effective to hybridize any polynucleotide having a complementary sequence of at least 15 bases thereto; and

detecting the presence of the DNA-complementary polynucleotide hybrid.

37. The method of claim 36, further comprising when the polynucleotide is contained in cells, lysing the cells to expose the polynucleotides therefrom.

38. A method of detecting the presence of an RNA sequence encoding a polypeptide having the antibody binding activity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least one of the light chains of clotting factors V and VIII or a fragment thereof in a sample, comprising

providing a sample suspected of comprising the RNA;

adding thereto a hybridization effective amount of the coding strand of the polynucleotide sequence of claim 28 in single stranded form under conditions effective to hybridize any RNA having a complementary sequence of about at least 15 bases thereto; and

detecting the presence of the polynucleotide-RNA hybrid.

39. The method of claim 38, further comprising when the RNA is contained in cells, lysing the cells to expose the RNA therefrom.

40. A method of detecting the presence in a sample of an RNA sequence encoding a polypeptide having the antibody binding activity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least a portion of one of the light chains of clotting factors V and VIII or a fragment thereof, comprising

providing a sample suspected of comprising the RNA;

adding thereto a hybridization effective amount of an oligoribonucleotide complementary to at least a portion of the polyribonucleotide sequence of claim 31 under conditions effective to hybridize thereto RNA having a complementary sequence of at least about 15 bases; and

detecting the presence of the polyribonucleotide-RNA hybrid.

41. The method of claim 40, further comprising

when the RNA is contained in cells, lysing the cells to expose the RNA therefrom.

42. A method of detecting the presence in a sample of a polynucleotide sequence encoding a polypeptide having the antibody binding activity of the about 46 kDalton HMFG differentiation antigen and/or homology to at least a portion of one of the light chains of clotting factors V and VIII or fragments thereof, comprising

providing a sample suspected of comprising the polynucleotide;

melting double stranded polynucleotide present in the sample;

adding thereto a hybridization effective amount of the RNA sequence of claim 31 under conditions effective to hybridize thereto any polynucleotide having a complementary sequence of at least 15 bases; and

detecting the presence of the RNA-complementary polynucleotide hybrid.

43. The method of claim 42, further comprising when the polynucleotide is contained in cells, lysing the cells to expose the polynucleotides therefrom.

44. A DNA segment comprising an anti-sense sequence to the coding strand of the polynucleotide of claim 25 of about 15 to 2000 nucleotides.

45. A pharmaceutical composition, comprising

a therapeutically effective amount of the anti-sense DNA sequence of claim 44; and  
a pharmaceutically-acceptable carrier.

46. A method of treating breast cancer in a subject in need of such treatment comprising administering to the subject a composition comprising a therapeutically effective amount of the anti-sense DNA segment of claim 44.

47. The method of claim 46, wherein the composition is administered by a route selected from the group consisting of parenteral, intravenous and intrabreast routes.

48. An immunoassay kit comprising, in separate containers  
the monoclonal antibody of claim 9; and  
anti-antibody immunoglobulin.

49. An antibody detecting kit comprising, in separate containers  
the polypeptide of claim 1; and  
anti-antibody immunoglobulin.

50. A fusion protein kit comprising, in separate containers  
the fusion protein of claim 6;  
a monoclonal antibody having specificity for a polypeptide which has the antibody binding specificity of the about 46 kDalton HMFG differentiation antigen

an anti-second polypeptide monoclonal antibody;  
and  
anti-antibody immunoglobulin.

51. An anti-breast cancer therapeutic kit comprising, in separate containers the monoclonal antibody of claim 9; and an anti-cancer therapeutic agent selected from the group consisting of immunotoxins and radionucleides.

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